

COLUMN: *Ethical Questions To Ponder*

Involvement of Professional Medical Writers in Manuscripts - A Blessing or a Curse?

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If your journal receives a manuscript where assistance from a professional medical writer has been declared, do you:

- a. Decline to review the manuscript as your journal bans manuscripts that have been prepared with medical writing assistance?
- b. Become concerned about the credibility of the manuscript, fearful that the manuscript may not be presenting the data in a fair and objective manner?
- c. Anticipate that at least somebody has read your 'Instructions to Authors' and that the manuscript would have been prepared in an ethical manner, will meet your submission requirements, be easy for your voluntary peer-reviewers to read and understand, and be quick for your staff to edit?

I have encountered answers a, b, and c during the last ten years in my organization, where our PhD-qualified medical writers have assisted more than 1,000 authors from around the world. I believe (as you might expect) answer c should be the most appropriate response.

In this brief article, my aim is to convince you that involving professional medical writers in manuscripts should be a blessing, not a curse. To achieve this aim, I will need to:

- (1) differentiate professional medical writers from ghostwriters;
- (2) reinforce the legitimate role of professional medical writers; and
- (3) direct you to a practical tool that will allow you to evaluate whether authors have used medical writing assistance appropriately.

Professional Medical Writers Are a Blessing (Ghostwriters Are a Curse)

Whether medical writing assistance is a blessing or a curse for your journal depends on whether the assistance has been provided by a professional medical writer or a ghostwriter. The two are not the same¹. Whereas professional medical writers are aware of, and abide by, guidelines for ethical medical writing practices, ghostwriters are not aware of these guidelines or deliberately choose to ignore them². Professional medical writers declare their involvement and funding source, and ensure authors control content³. In contrast,

¹ Woolley KL (2005) Letter to the Editor. AMWA Journal 20(4): 184.

² Götzsche PC, Kassirer JP, Woolley KL, Wager E, Jacobs A et al (2009) What should be done to tackle ghostwriting in the

medical literature? PLoS Med 6(2): e23.

³ Woolley KL (2006) Goodbye Ghostwriters! How to work ethically and efficiently with professional medical writers. Chest 130(3): 921-923.

ghostwriters hide their involvement and funding source, and may try to control content³. Ghostwriting is an unethical practice and should be eradicated².

The good news for editorial staff is there are signs professional medical writers may be winning the war against ghostwriters. Professional medical writing associations in North America (American Medical Writers Association; www.amwa.org), Europe (European Medical Writers Association; www.emwa.org), and the Asia-Pacific region (ARCS; www.arcs.com.au) have a vested interest in ridding ghostwriters from the medical writing profession. These associations reinforce ethical medical writing practices through their position statements, membership criteria, and continuing professional education programs. Reassuringly, surveys of medical writers in 2005 and 2008 indicate more medical writers are becoming familiar with guidelines for ethical medical writing practices and more medical writers are declaring their involvement⁴. Be under no illusion...there is still much work to be done, but these results suggest the prevalence of declared medical writing assistance may increase; currently, approximately 6% of publications in high-ranking, international,

peer-reviewed journals have declared medical writing assistance⁵. In the future, editorial staff are likely to become increasingly exposed to declared medical writing assistance – they will need to decide whether such assistance is legitimate.

Legitimate Role for Professional Medical Writers

Academics and journal editors from around the world have reinforced that professional medical writers can have a legitimate role in helping authors prepare manuscripts, providing appropriate disclosures are made^{2,6}. There is the belief, although limited empirical evidence, that professional medical writers can help authors prepare high quality manuscripts in a timely manner^{7,8}. Professional medical writers may also help authors edit previously rejected manuscripts to enhance the probability of publication success⁹. Authors tend to seek professional medical writing assistance when they are limited by time, language, or manuscript preparation experience³. Rather than be frowned upon, such assistance may help address the ethical and scientific problems of nonpublication, given that almost half of the

4 Jacobs A, Hamilton C (2009) Decreased evidence of ghostwriting in a 2008 vs 2005 survey of medical writers. *The Write Stuff* 18(2):118-123.

5 Woolley KL, Ely JA, Woolley MJ, Findlay L, Lynch FA et al (2006) Declaration of medical writing assistance in international peer-reviewed publications. *JAMA* 296(8): 932-934.

6 Hirsch LJ (2009) Conflicts of interest, authorship, and disclosures in industry-related scientific publications: the tort bar and editorial oversight of medical journals. *Mayo Clinic Proc* 84(9): 811-821.

7 Phillips SG (2009) Authorship and writing practices in the health care industry. *AMWA Journal* 24(1): 4-8.

8 Woolley KL, Ely J, Woolley MJ, Lynch F, McDonald J et al (2005) Declaration of Medical Writing Assistance in International, Peer-Reviewed Publications and Effect of Pharmaceutical Sponsorship. Abstract presented at the 5th International Congress on Peer Review and Biomedical Publication. Available: <http://www.ama-assn.org/public/peer/program.html>. Accessed 1 September 2009.

9 Woolley KL, Barron JP (2009) Handling manuscript rejection: insights from evidence and experience. *Chest* 135(2): 573-577.

medical research results presented at conferences are never published in full¹⁰.

Professional medical writers may also have a legitimate role in minimizing the risk of misconduct. This statement may be surprising to some, particularly those who confuse professional medical writers with ghostwriters. However, evidence from the largest study conducted to date on retracted publications shows publications with declared medical writer involvement have rarely had to be retracted from the literature due to misconduct¹¹. The same cannot be said of publications without declared medical writing assistance. In practical terms, this research suggests that if editors do receive manuscripts with declared medical writing assistance, they are unlikely to have to go through the emotional and financial minefield of issuing a retraction for misconduct.

Although some journal editors may contemplate banning any manuscripts with medical writing assistance, this strategy, when implemented, has been short-lived¹² and has not been embraced by many other editors. Indeed, this strategy may exacerbate the problem of nonpublication and cause more work for editorial staff if they have to manage an increasing number of poorly written manuscripts that do not comply with journal requirements. This latter prospect is unlikely to be welcomed by busy editorial staff¹³.

Evaluating the Appropriateness of Medical Writing Assistance

If you accept that professional medical writers can have a legitimate role in preparing manuscripts and you receive a manuscript with declared medical writing assistance, then you will no doubt want to know whether the authors have used medical writing assistance appropriately. This is where a practical tool could help you. With input from journal editors and professional medical writers from around the world, my colleagues and I developed a five-question, structured instructional checklist; authors complete this checklist to show they have used medical writing assistance appropriately (Table 1)². This checklist is freely available and can be downloaded from the PLoS Medicine (www.plosmedicine.org) or the EQUATOR network (www.equator-network.org) websites. Journal editors are encouraged to require authors who use medical writing assistance to complete and submit this checklist with their manuscript.

The first question in the checklist, which prompts authors to ensure medical writer involvement is appropriately acknowledged, could help raise awareness of authorship criteria and reduce poor authorship attribution practices. The second question reinforces the need for transparency and

¹⁰ Scherer RW, Langenberg P, von Elm E (2007) Full publication of results initially presented in abstracts. *Cochrane Database Syst Rev*: MR000005.

¹¹ Woolley KL, Woolley MJ, Lew R, Bramich N, Ely J et al (2009) Round Up the Usual Suspects? Involvement of Medical Writers and the Pharmaceutical Industry in Retracted Publications. Abstract presented at the 6th International

Congress on Peer Review and Biomedical Publication. Available: http://www.ama-assn.org/public/peer/program_2009.pdf. Accessed 1 September 2009.

¹² Mayer DK, Mahon SM, Eaby B (2009) Writing for hire: advice for authors (and readers). *Clin J Oncol Nurs* 13(2): 131-132.

¹³ Salkin I (2009) Editing a biomedical journal: a personal view. *Editorial Office News* January 2(1): 5-10.

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continued

disclosure in relation to the source of funding for medical writing services. The third and fourth questions focus on author control over the manuscript. The third question reinforces that the author(s) should make the final decision about the main points communicated in the manuscript. The fourth question reinforces that the author(s) should make the final decision about the outcomes and data to include in the manuscript. This question also reinforces to authors that they should not hide relevant, non-supportive data. Confirmation of author control over the main points, outcomes, and data should provide a level of reassurance to editorial staff and reviewers and, ultimately, to readers. The fifth question, which requires the authors to confirm ethical medical writing practices were followed during the manuscript preparation process, provides the checklist with some ‘teeth’. This question

alerts authors and medical writers that the journal editor may probe into the medical writing practices used. Even if a journal’s limited resources mean the risk of an audit is low, this question reinforces to authors and writers that ethical medical writing guidelines are readily available and they should be followed.

In conclusion, the involvement of professional medical writers in manuscripts can be a blessing, not a curse. Professional medical writers, but not ghostwriters, can have a legitimate role in helping authors prepare manuscripts. Editorial staff now have free access to a practical tool that can help them evaluate whether authors have used such assistance appropriately.



Table 1. Checklist for Authors Using Medical Writers: A Practical Tool to Discourage Ghostwriting*

Professional medical writers can be legitimate contributors to manuscripts, but ghostwriting is dishonest and unacceptable.

Authors: If a medical writer contributed to the preparation of your manuscript, you must answer the questions below.

Question		Answer	
		No	Yes
1	(a) Did the medical writer meet the three criteria for authorship, as specified by the International Committee of Medical Journal Editors?		
	(b) If not, has the writer been identified in the acknowledgments or as directed by the journal?		

Table 1. continued

	Question	Answer	
		No	Yes
2	Has the source of funding for the medical writer’s services been identified in the acknowledgments or as directed by the journal?		
3	Did the author(s) make the final decision on the main points to be communicated in the manuscript, particularly in the conclusion?		
4	Did the author(s) make the final decision on the primary and secondary outcomes and relevant data to be reported in the manuscript?		
5	If requested by the journal, can the medical writer provide evidence that the manuscript was prepared in accordance with international guidelines for ethical medical writing (e.g., Uniform Requirements for Manuscripts Submitted to Biomedical Journals; Good Publication Practice for Pharmaceutical Companies; Position Statements from the European or American Medical Writers Associations, or the International Society for Medical Publication Professionals)?		

* This checklist was first published in PLoS Medicine² and is available for use under the Creative Commons Attribution License.

Have You Fallen Behind?

If you’ve gotten behind in checking the weekly news items on the ISMTE home page, you can catch up by going to the ISMTE Resources page at <http://ismte.org/resources.html>. Scroll down to ‘News from the world of publishing’ and click on the ‘archive’ link.